

REMARKS

The syntax of claim 7 has been improved as requested. Withdrawal of the objection thereto is respectfully requested.

It is respectfully submitted that the rejection of claims 1, 3, 7, 9, 10 and 14 under 35 USC § 112 should be withdrawn since there is support for the range of about 0.6 to 24 MIU/ml, and this range does not constitute new matter.

The text on page 3 of the application refers to Tables 1, 2 and 3 as setting forth formulations containing 0.6 or 1 MIU/ml. Reference to those tables clearly shows one skilled in the art that these numbers are approximate ("about") rather than absolute and provides guidance concerning the extent of the range. As one example, the IFN/3 formulation in Table 2, actually contained 549425 IU/ml (0.549425 MIU/ml). It is respectfully submitted that this establishes that the recitation of "about" is not new matter.

It is, of course, proper to construct a range from any portion of the application as long as one skilled in the art would recognize that the applicant had possession of the invention at the time of filing. See, e.g., *In re Blaser*, 194 USPQ 122 (CCPA 1977) and *In re Wertheim*, 191 USPQ 98 (CCPA 1976). The Office Action acknowledges that there is support for the range of 0.6 to 1 MIU/ml, and also for 12 MIU/ml and 24 MIU/ml. When viewed in the context of what the application states about these values, it is clear that the applicant had possession of the entire 0.6-24 MIU/ml range.

This application as filed states that the invention constitutes a liquid formulation of interferon-beta, a polyol, a non-reducing sugar or amino acid in an appropriate buffer (page 2, lines 9-12) and original claim 1 did not have any MIU limitation. At pages 2 to 4, it is indicated that to study the effect of some isolated parameters, a series of formulations having different amounts of interferon were

prepared, and it will be noted that the stability studies with mannitol in Tables 4 and 5 actually contain more than 1 MIU/ml, namely, 1.2 and 1.1 MIU/ml of the interferon (after mathematical rounding), respectively. Following this disclosure, examples of pharmaceutical formulations and their preparation are set forth on pages 5 and 6. Those examples contain 1, 12 and 24 MIU/ml of the interferon. No reason to prepare the 12 and 24 MIU formulations other than as examples of the invention is given anywhere in the text. The application thus fully discloses and teaches those skilled in the art how to make and use formulations having MIU/ml values at the extremes of the claimed range, as well as values within that range. While it is apparent that 0.6-1 MIU/ml is a preferred range, it is also clear that the applicants had possession of an invention (formulations) containing a variety of MIU/ml values ranging from about 0.6 to 24 at the time the application was filed.

In light of the foregoing, it is respectfully submitted that this case is in condition to be allowed.

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Respectfully submitted,

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